

Community Pharmacies Mood Intervention Study (CHEMIST)

Participant Information Sheet

We invite you to take part in a research study

- Before you decide whether to take part, we would like to tell you why the research is being done and what it will involve.
- Please take the time to read this information sheet. Discuss it with your friends and relatives if you wish.
- Ask us if there is anything that is not clear or if you would like more information.
- Take time to decide whether or not you wish to take part. If you choose not to take part, this will not affect the care you get from your GP or your pharmacy.
- Thank you for reading this information sheet. If you decide to take part please complete the **consent form and background information** and post it back to us in the prepaid envelope provided.

Important things you need to know

- We want to find out whether community pharmacies can support people with long term health problems to maintain a positive mood.
- We have designed a form of support called **Pharmacy Support**. Some people in the study will be offered this support via their community pharmacy, other people will continue to receive their usual care.
- By asking you to complete a questionnaire at the beginning of the study and again four months later, we hope to understand more about what helps people.
- You can stop taking part in the study at any time, without giving a reason.

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How to contact us

If you have any questions about the study please talk to:

Dr Liz Littlewood
Department of Health Sciences
University of York
Heslington,
York, YO10 5DD
Tel: 01904 321828

A friend or relative may speak to us on your behalf if you wish. There is an answering machine available 24 hours a day, so please leave a message and someone will return your call as soon as possible.

We also have a study website at:
<https://www.york.ac.uk/healthsciences/research/mental-health/projects/chemist/>

1 Why we are doing this study?

What are we studying?

The study is trying to find out how to support the health and wellbeing of adults with ongoing long term health problems. It is important to find out if a new and different way of providing support to people is better than the care they usual receive.

Why do we think this is important?

The way that people feel can affect many parts of their life. People with long term health problems may sometimes feel low or unhappy. Feeling low is often linked to other things like sleeping badly, not wanting to see people, or having little or no motivation to do things.

Many people have to deal with long term health problems that make doing the things they used to do increasingly difficult. For example, not being able to move about as easily can lead to a loss of independence and feelings of being isolated and lonely. Things like this can affect how people feel and can sometimes lead to people feeling down or unhappy.

Why are we running the study in community pharmacies?

We are trying to learn more about how community pharmacies can offer support to help people to try to nip such problems in the bud. Pharmacies see many people with long term health conditions. We think community pharmacies may be a good place to offer support to people with low mood before these feelings get too bad. Pharmacies now offer a range of health support services and the support we are looking at in the study is similar to these.

2 Why am I being asked to take part?

A number of community pharmacies and GP practices are supporting this study. They are contacting people who have a long term health condition to see if they may be interested in taking part. Your pharmacy has identified you as someone who may be suitable to take part. You may also have seen posters advertising the study in your area and contacted the research team directly. We hope to get 100 people to take part in the study.

3 How the study works

How do we find out whether Pharmacy Support works?

We don't know yet whether this new type of pharmacy support and care is any better than the care already offered. We need to compare the two methods of giving care to see if there is a difference. This will mean that half the people in the study will be offered this new form of care and half will get usual care. Usual care means you will continue to receive your usual NHS care.

How is it decided who will be offered Pharmacy Support?

You will be asked to complete a questionnaire before you start the study. You will then be put into one of two groups, either **Pharmacy Support** or the **usual NHS care** you receive.

A computer will choose which group you are in – this is called 'randomisation'. It is a bit like rolling a dice to decide and it means you have an equal chance of being in either of the two groups. No treatment will be withheld and both groups will continue to receive all the care and support they usually do whilst taking part in the study.

4 What will happen to me if I take part?

If you are interested in taking part you will need to complete the enclosed **consent form and background information** and return this to the study team in the prepaid envelope provided (you do not need a stamp). You will then be contacted by a researcher who will ask you some questions to check whether you are suitable for the study.

At this point you will also have the opportunity to raise with the researcher any questions you might have about the study. You do not have to enter the study unless you feel completely happy with what you are being asked to do.

Collecting information

If you are suitable to take part and you are happy to proceed with the study, we will ask you to complete a questionnaire about yourself. It is important for us to know how things are for you before you start the study. The researcher can either arrange to ask you these questions over the telephone, or we can send you the questionnaire to complete and post back to us in a prepaid envelope. You can ask family or friends to help you complete it too.

When you have completed the questionnaire, a researcher will be able to tell you which one of the two groups you have been allocated to.

Group 1 Pharmacy Support

If you are placed in this group, you will be offered the Pharmacy Support. This will involve a Healthy Living Advisor from your community pharmacy working with you to plan changes that aim to improve your mood and overall wellbeing. A Healthy Living Advisor will contact you to arrange a convenient time to meet you or speak with you.

The first meeting with your Healthy Living Advisor may take place at your pharmacy or over the telephone. After this, you will speak with your Healthy Living Advisor up to a total of six times, normally on a weekly basis, over a period of four months.

You will be provided with a booklet to help you think about your difficulties and what you may be able to do to improve some of them. During your weekly sessions, your Healthy Living Advisor will discuss this with you and a range of issues you may have. For example, how you have been feeling since you last spoke, and how to deal with any difficult feelings you have had since then. Each time you speak it will last about 15-20 minutes. At the end of each session, you and your Healthy Living Advisor may plan some things for you to do before you next speak.

We may ask for your permission to audio record some of your sessions with your Healthy Living Advisor. If you do not wish to be recorded you can still take part in the study.

Taking part in this study will not require you to travel further than your community pharmacy. You will normally speak to your Healthy Living Advisor over the telephone.

Group 2 Usual NHS Care

If you are placed in the usual NHS care group, your care will continue as normal. You will still play a vital part in the study by being in this group.

We would still like you to complete all of the study questionnaires. The information you give us will help us to see whether the Pharmacy Support care gives better results than the usual care people generally receive. To do this it is important that we compare the two different groups.

Follow up

Four months after you start the study we will contact you again to ask you a further set of questions to see how you are feeling now. These questions will be similar to those we asked you at the beginning of the study. This information will help us see whether the new Pharmacy Support care is better than the usual care people generally receive.

A researcher can either arrange to ask you these questions over the telephone, or we can send you the questionnaire to complete and post back to us in a prepaid envelope. You can ask family or friends to help you complete it too.

Opportunity to provide your feedback

You may also be asked if you would be happy to speak with a researcher to discuss your views about mental wellbeing and the new way of giving support to people through a community pharmacy. We will ask for your permission for this and your permission to audio record your feedback. We will remove your name when we write up the feedback and your name will not appear in any written reports of the research. If you do not wish to be recorded, you can still give us your feedback. We will only ask a small number of people to give us their feedback and doing this is voluntary.

5 Possible benefits and disadvantages of taking part

What are the possible benefits of taking part?

We cannot promise that taking part in the study will help you. Taking part could help improve the support offered to people suffering with low mood in the future. The type of support we are offering has been shown to help people in GP practices. You may be offered this additional

pharmacy support which is not usually available to people from their community pharmacy.

What are the possible disadvantages of taking part?

Taking part in the study will take up some of your time. It takes time to complete the study questionnaires. People in the Pharmacy Support group will spend some time reading the booklet, speaking with a Healthy Living Advisor and working through the activities.

6 More information about taking part

Do I have to take part?

No, it is up to you to decide whether to take part or not. Please feel free to contact us if you would like more information, or to ask us any questions. Our details are on the front page of this information sheet.

You will be asked to sign a consent form if you decide to take part. We will send you a copy of this for you to keep. Please also keep this information sheet as well. Even if you agree to take part in the study, you are still free to stop at any time, without giving a reason. The standard of care you receive from your GP or pharmacy won't change if you decide not to take part, or if you decide to stop taking part once you have joined.

Will I receive any payment for taking part?

We will pay the postage costs in relation to the study. We would also like to provide a small thank you payment of £5 for each of the two times you complete the study questionnaires.

However, we would like to draw your attention to the fact that these payments would be

considered by HMRC as income and so it may affect your tax liability and/or your entitlement to any benefits you receive. As we don't know your circumstances, we will not deduct any UK income tax, nor National Insurance for you. Therefore it would be up to you to let the appropriate agencies know if this is relevant to your circumstances.

If you would prefer, it is fine for you to take part in this study without accepting these thank you payments. We are not able to offer any further expenses or payments for taking part in the study.

What will happen if you are not suitable to take part in the study?

If you are found not to be suitable for the study, you will not be placed in the Pharmacy Support or Usual NHS Care groups, and will not be asked to complete the study questionnaires. Your involvement in the study will finish at this point and the care you normally receive will continue as usual. A researcher will speak to you about this.

Will your GP be involved?

We will tell your GP if you are found to be suitable for the study and you agree to take part. We will also ask for your permission to get in touch with your GP if we have any concerns about your health whilst you are helping us with the study.

What will happen to information collected about me during the study?

We will treat any information you give us in confidence. We will store all of your information safely and securely. We will not mention your name in any publications about the study and we will make sure that no individuals can be identified in the study results.

Sometimes we are asked to share information we collect in studies with other researchers who are looking at similar ways to improve healthcare. With your agreement, we would like to be able to share the information we collect about you as part of this study. We will always remove all identifiable information before we share your information and this is controlled by strict University of York procedures.

It might be that research which is similar to this study is carried out in the future, either by us or by other researchers. With your agreement, we would like to send you information about these related studies. The information will only be sent to you by a member of our study team. We will not pass your personal details to anyone outside of the study team. This would be controlled by strict University of York and NHS Trust procedures.

We will keep the information you give us as part of the current study safely for 10 years after the study ends. It will then be destroyed securely. Paper records will be handled by the study team and kept in locked cabinets. Electronic records will be held on a secure computer server at the York Trials Unit. Only authorised members of the study team will have access to your information.

What if there is a problem?

If you have concerns about the study or if there is anything you would like to ask about the study, please get in touch with us. Our contact details are at the front of this information sheet. If you would prefer to speak to the Chief Investigator, Dr David Ekers, you can contact him directly (Tel: 01642 451597, Email: david.ekers@nhs.net).

We do not expect any harm to come to you from being in this study. However, if you wish to complain or have any concerns about any aspect

of the way you have been approached or treated during the course of the study, the normal NHS complaints processes are available to you through the Patient Advice and Liaison Service (PALS) 0800 052 0219.

What will happen to the results of the study?

When the study has finished and the results have been published, we will send a summary of the study results to everyone who has taken part in the study. You can contact your pharmacy or the study team directly if you decide not to take part in the study, but would still like to receive a summary of the results.

Who is organising and funding the study?

This study is organised by a group of Universities (York, Keele, Newcastle and UCL) and Tees, Esk and Wear Valleys NHS Foundation Trust. This group is working with community pharmacies and GP practices around the North East area.

The study has been funded by the Department of Health's National Institute for Health Research Public Health Research programme.

The study has been reviewed by an independent group of people, called a Research Ethics Committee. This is to protect your safety, rights, wellbeing and dignity. This study was looked at and approved by the North East – Newcastle & Tyneside 2 Research Ethics Committee.

Is there anyone else I can talk to about the study?

Please contact INVOLVE (Tel: 02380 595628) for general information about research. Please contact MIND (Tel: 0300 123 3393) for more general information about mental wellbeing.

7 What do I need to do now?

What do you need to do if you would like to take part in the study?

Please fill in and sign the **consent form and background information** and return this in the pre-paid envelope provided. You do not need a stamp. Please contact us if you would like help with completing this form. If you decide to take part in the study, a researcher will contact you to discuss this. If you are found to be suitable for the study, we will write to you to confirm this. We will also let your GP know that you are involved in the study.

Do I need to do anything if I don't want to take part in the study?

No, you do not need to do anything if you do not want to take part in the study. If you do not want to take part, you don't have to, it's up to you. The care you receive from your GP or pharmacy will not be affected in anyway.

Thank you for taking the time to consider taking part in this study.